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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/559,013	04/26/2000	Toshiro Ono	L0461/7086(JRV)	1882

7590 04/28/2005

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/559,013	ONO ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 54,56,60,62,64,66,76,133,134 and 137 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 54,56,60,62,64,66,76,133,134 and 137 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____.

DETAILED ACTION

1. After review and reconsideration, the finality of the Office action of mailed April 20, 2004 is withdrawn.

2. Claims 54 and 62 have been amended. Claims 15, 19, 41 and 122-132 have been canceled. Claims 54, 56, 60, 62, 64, 66, 76, 133, 134 and 137 are pending and under consideration.

3. Acknowledgment is made of applicant's claim to an earlier effective filing date through provisional application 60/168,353. Upon review of the '353 application it is noted that SEQ ID NO:23 is missing from the disclosure and the sequence listing does not contain a polynucleotide sequence comprising 1895 nucleotides. The '353 application is deemed to lack insufficient written description of SEQ ID NO:23, and therefore the instant application will be given the effective priority date of April 26, 2000.

4. Sections of Title 35, U.S. code not found in this action can be found in a previous action.

5. Claim 137 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how claim 137 further limits claim 76. Claim 37 carries the limitation "wherein the pair of isolated nucleic acid molecules selectively amplify". Claim 76 recites the method objective of "kit for detecting the presence of the expression of a cancer associated antigen precursor" . The ability of the pairs of nucleic acids to selectively amplify the cancer associated antigen precursor would be inherent in claim 76, because without such ability, the isolated nucleic acid pairs would be non-operative. Further, it is noted that claim 76 requires that the pairs do not overlap each other in sequence, thus avoiding "primer-dimer" which would contribute to the selective amplification of the cancer associated antigen precursor.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 54, 56, 60, 64, 66, 133 and 134 are rejected under 35 U.S.C. 102(e) as being anticipated by Jacobs et al (U.S. 2003/0044935, priority to 09/098,588, filed Jun 17, 1998).

Claim 56 is drawn in part to a full-length complement of an isolated nucleic acid molecule consisting of a fragment of SEQ ID NO:23 having at least 8 nucleotides, provided that the isolated nucleic acid molecule is not identical to SEQ ID NO:33. Claim 133 embodies the nucleic acid molecule of claim 56 wherein the fragment is at least 10, 12, 14, 16, 18, 20, 22, 24, 26 or 28 nucleotides. Claim 14 embodies the isolated nucleic acid molecule of claim 56 wherein the molecule encodes a polypeptide of a fragment of a polypeptide which binds a MHC receptor or an antibody.

Jacobs et al disclose SEQ ID NO:92 which is a 29-mer oligonucleotide consisting of the complement of a fragment of the instant SEQ ID NO:23 from nucleotide 417 to nucleotide 446. The translation of the polynucleotide sequence of SEQ ID NO:92 into an amino acid sequence would render a polypeptide fragment which would bind to an antibody, because the art teaches that an antigenic epitope minimally comprises at least six contiguous residues of a polypeptide. It is noted that 09/098,588 application discloses the identical 29-mer as SEQ ID NO: 26.

Jacobs et al disclose ga63_6 (SEQ ID NO:77) which would hybridize to the complementary sequence of the instant SEQ ID NO:23. Jacobs et al disclose that the polynucleotides were isolated from a human adult testes library and encode the polypeptide of SEQ ID NO:78 (page 74, paragraphs 1842 and 1843), polynucleotide that hybridize under

stringent conditions to SEQ ID NO:77 (page 94, paragraph 2114), the linking of the polynucleotide to expression control sequences for the recombinant production of the protein (page 95, paragraph 2117), host cells, including mammalian cells (page 95, paragraph 2118), which would inherently express MHC I. further, Jacobs et al discloses that tumor cells which lack MHC I or class II molecules or which fail to express sufficient amount of MHC I or MHC II molecules can be transfected with a nucleic acid encoding all or a portion of an MHC I or MHC II molecule and the transfection of a DNA encoding a peptide having the activity of a B lymphocyte antigen in conjunction with the DNA encoding the appropriate class I or II associated protein (page 99, paragraph 2153) which fulfills the specific embodiment of claim It is noted that 09/098,588 application discloses the identical ga63_6 as SEQ ID NO:11.

The reference does not specifically teach that the protein encoded by SEQ ID NO:77 (SEQ ID NO:78) is a cancer assoicated antigen precursor. However, the claimed polynucleotide appears to be able to hybridize to the complementary strand of SEQ ID NO:23 under stringent conditions and differs from the instant SEQ ID NO:23 by less than 0.1%. ("T" in place of "C" at nucleotide 142 and "C" in place of "T" at nucletide 995). The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable diffrences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

8. Claims 54, 56, 60, 64, 66, 76, 133, 134 and 137 are rejected under 35 U.S.C. 102(a) as being anticipated by Bandman et al (WO 00/09709).

Claim 54 is drawn to an isolated nucleic acid molecule comprising a nucleic acid molecule selected from the group consisting of complements of nucleic acid sequence which hybridize under stringent conditions to SEQ ID NO:23 and which code for a cancer associated antigen precursor and nucleic acids which encode the same protein as the nucleic acids of part a. Claim 60 is drawn to an isolated expression vector comprising an isolated nucleic acid of claim 54 operably linked to a promoter. Claim 62 is drawn to an isolated expression vector comprising

an isolated nucleic acid of claim 54 and a nucleic acid encoding a MHC molecule. Claim 64 is drawn to an isolated host cell transformed or transfected with the expression vector of claim 60. Claim 66 is drawn to the isolated host cell of claim 60 further comprising a nucleic acid encoding a MHC molecule.

Claim 76 is drawn to a kit for detecting the expression of a cancer associated antigen precursor comprising a pair of isolated nucleic acid molecules which comprising 12-32 nucleotides which hybridize to SEQ ID NO:23 and a complement of SEQ ID NO:23 nucleic acids which encode the protein encoded by SEQ ID NO:23 or complements of said nucleic acids, and wherein the pair of isolated nucleic acid do not overlap each other. Claim 56 is drawn to a fragment of SEQ ID NO:23 of at least 8 nucleotides or full length complements of said fragment provided that the fragment is not SEQ ID NO:33. Claim 133 embodies the isolated nucleic acid of claim 56 wherein the fragment has a size selected from the group consisting of 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 50, 75, 100 and 200 nucleotides. Claim 134 embodies the isolated nucleic acid of claim 56 wherein the nucleic acid encodes a polypeptide, or a fragment thereof which binds a MHC receptor or an antibody.

Bandman et al disclose SEQ ID NO:30 which is identical to the instant SEQ ID NO:23. Bandman et al disclose that SEQ ID NO:30 encodes PPRG-10 (SEQ ID NO:10) (page 54, Table 30). Bandman et al disclose an expression vector comprising at least a fragment of the polynucleotide encoding the PPRG-10 polypeptide, and a host cell comprising said vector (page 5, lines 13-16). Bandman et al disclose mammalian cells as an embodiment of a host cell (page 22, lines 19-26), which fulfills the specific embodiments of claim 66 because the mammalian host cell would comprising an endogenous nucleic acid encoding an MHC I molecule. Bandman et al disclose that immunogenic or antigenic fragment of PPRG are preferably at least 14 amino acids which retain some of the immunological activity of PPRG, and a preferred embodiment of nucleotide 1190 to 1234 of SEQ ID NO:30 which encodes an immunogenic peptide (page 8, lines 2-5, page 15, lines 31-32 and page 16, lines 8-9) and which fulfills the specific embodiment of claim 134 because a fragment of the immunogenic peptide would bind to the MHC and/or an antibody. Bandman et al disclose polynucleotide sequence which are capable of hybridizing to the polynucleotide sequence of SEQ ID NO:30 under various conditions of stringency (Page 17, line 17 to page 18, line 15). Bandman et al disclose that the polypeptide sequence may be cloned

into recombinant DNA molecules to direct the expression of PPRG, which fulfills the specific embodiment of claim 60 requiring an operable link to a promoter (page 19, line 32 to page 20, line 3). Bandman et al disclose that cells comprising PPRG can be identified by PCR amplification (page 23, line 30 to page 24, line 1 and page 38, lines 1-7). Bandman et al disclose that the polynucleotides encoding PPRG may be used for the diagnosis of disorder associated with expression of PPRG (page 36, lines 12-13 and page 37, lines 29-34) which include Cancer for SEQ ID NO:30 (Table 3, page 61). thus the detection of SEQ ID NO:30 or the polynucleotides encoding SEQ IDNO:30 would be commensurate with the detection of a cancer associated antigen, because Bandman et al disclose that the expression of SEQ ID NO:30 is associated with cancers.

9. All other rejections and objections as set forth in the previous Office action are withdrawn in light of applicants amendments.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
4/26, 2005

Karen A Canella

KAREN A. CANELLA PH.D
PRIMARY EXAMINER